K102703.

SYBRON DENTAL SPECIALTIES

JAN - 5 2011

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
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Wendy Garman - Contact Person

Date Summary Prepared: December 2010

Device Name:

- Trade Name – *Build-It Total Core*
- Common Name – Dental Composite Restorative Material
- Classification Name – Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- *Build-It F.R., K000211,* Pentron Clinical
- *Cement-It All Purpose, K060698,* Pentron Clinical

Device Description:

Build-It Total Core is a dual-cure, self-adhesive composite with a continuous fluoride release. B*uild-It Total Core* utilizes 4-MET technology to adhere to dentin and cut enamel without a separate bonding agent. Ideal flow characteristics, esthetic and contrast shades, and outstanding physical properties make *Build-It Total Core* an indispensable tool in every clinician's armamentarium.

Intended Use of the Device:

Build-It Total Core is indicated for use as a core build up material on vital and non-vital teeth, sealing root canal openings, cavity floor liner, post cementation, restorative material and dentin replacement material.

Substantial Equivalence:

Build-It Total Core is substantially equivalent to two other legally marketed devices in the United States. *Build-It Total Core* functions in a manner similar to and is intended for the same use as *Build-It F.R*, manufactured by Pentron Clinical. Its self-adhering properties are equivalent to *Cement-It All Purpose,* currently marketed by Pentron Clinical as *Breeze*. *Build-It Total Core* is similar to *Build-It F.R* in that it is a fiber reinforced, dual cure post and core build-up resin composite material which is used for tooth restorations. *Build-It Total Core* differs from *Build-It F.R* in that it utilizes 4-MET technology to adhere to dentin and cut enamel without a separate bonding agent. *Build-It Total Core* is similar to *Cement-It All Purpose,* a self-adhering dental cement currently marketed by Pentron Clinical as *Breeze,* in that it has a similar formulation and it has self-adhering properties.

Non-Clinical Test Data

A biocompatibility study was completed, which demonstrates that the material is safe for its intended use. This 510(k) submission also includes data from bench testing used to evaluate performance characteristics of *Build-It Total Core* compared to the predicate devices, *Build-It F.R.* and *Cement-It All Purpose* currently marketed by Pentron Clinical as *Breeze*. The characteristics evaluated include water absorption and solubility, flexural and compression strength, linear expansion in water, fluoride release, and bond strength.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the biocompatibility studies and similar technological/performance characteristics as compared to the predicate devices, the clinical performance of *Build-It Total Core* is deemed to be substantially equivalent to the predicate devices, *Build-It F.R.* and *Cement-It All Purpose* currently marketed by Pentron Clinical as *Breeze*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 W. Collins Avenue
Orange, California 92867

JAN - 5 2011

Re: K102703
Trade/Device Name: Build-It Total Core
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 6, 2010
Received: December 7, 2010

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102703

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Device Name: *Build-It Total Core*

Indications For Use:

Build-It Total Core is indicated for use as a core build up material on vital and non-vital teeth, sealing root canal openings, cavity floor liner, post cementation, restorative material and dentin replacement material.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102703